5 BIOCOMPATIBILITY

INTRODUCTION

All medical devices, including patient examination and surgical gloves, must be safe and effective for the intended use. Therefore, devices such as gloves that contact the body must be biocompatible.

Biocompatibility data should be submitted for all medical gloves, including synthetic polymer gloves of all types and synthetic polymer-coated latex gloves, latex surgical gloves, **and** latex patient examination gloves. Because medical gloves are in direct contact with skin, a primary skin irritation study and a dermal sensitization study are appropriate. (See FDA, CDRH, ODE Blue Book Memorandum #G95-1 and ISO TC 10993 for further guidance.) Blue Book Memorandums are available from DSMA by phoning Facts-On-Demand at 30l-827-0111 or 800-899-0381.

ISO and most other standards are available from the American National Standards Institute (ANSI). 11 West 42nd Street, New York, New York 10036, Phone 212-642-4900, FAX 212-398-0023, http://www.ansi.org

Each 510(k) application should include the required biocompatibility test results and other information and data as described in this manual. FDA will ***not*** review an incomplete 510(k) application**.** A premarket notification [510(k)] application should contain an attached report for each major study or test program such as biocompatibility studies. All reports or attachments should be identified with the manufacturer's name, the pages should be numbered, and listed in the table of contents. Biocompatibility tests should be performed on finished gloves. For sterile devices, test data should include the results of tests performed using the finished sterilized devices. (Of course, biocompatibility tests may also be performed on raw materials in order to select qualified materials for use in the devices.)

To facilitate FDA review of the data, analysis, and conclusions in the application, the manufacturer and contract laboratory, if used, should check the:

- logical presentation of the biocompatibility data,
- scientific soundness of the test method and data analysis,
- relevance of the test program to the device and the intended use, and

- completeness of the summary report of the tests or studies.

The summary of test results should be presented in a table format in each report whenever possible. Each study or test attachment report should contain sufficient and well-organized information in reasonable detail so that the FDA reviewer can determine:

- what exact material or device was tested,
- what tests were performed,
- how the tests were performed, and
- what the test results were.

A description of the tests and the results obtained are essential; and reasonable and sufficient details of all test procedures and results should be submitted to FDA. For biocompatibility studies, manufacturers should use a standard scoring system for each test method, if a standard scoring system exists. Each test report should include the following:

- name and address of the manufacturer of the item tested,
- name and technical description of the item tested,
- name and address of the laboratory where the tests were conducted,
- test methods including the scoring method,
- number of samples and replicates tested,
- any control data needed to establish the validity of the test,
- the date when the tests were conducted,
- summary report(s) of results obtained, and
- analysis, interpretation of results, and conclusions.

When a study such as a biocompatibility study is conducted by an internal or contract laboratory to establish a company device specification and/or to obtain data for a submission to FDA, the device manufacturer should keep the **original** records of the study, as listed above, on file as part of their design verification records in the design history file (DHF). Do not submit the original records to FDA. During factory inspections, FDA investigators may ask to see these original records. For surgeon's gloves and for examination gloves if they become class II, these records are covered by §§820.3(i), 820.30(f) and 820.30(j).

SKIN IRRITATION AND DERMAL SENSITIZATION STUDIES

Anyone wishing to obtain clearance from FDA to market medical gloves including surgical and examination gloves in the United States should supply FDA with data from a Primary Skin Irritation Study and a Dermal Sensitization Study. The gloves used for biocompatibility studies should be finished gloves. That is, the gloves should contain the same colorants, fragrances, powders, lubricants, processing chemicals, etc., and be processed, packaged and, if appropriate, sterilized by the same methods as the gloves to be distributed. The need to repeat biocompatibility studies should be considered if subsequent changes are made in glove composition, manufacturing materials, or processing.

The following is a general discussion of how these skin irritation and dermal sensitization studies may be conducted. A list of laboratories that promote their ability to conduct these tests is printed at

the end of this chapter. The list may not be inclusive of all laboratories capable of providing this service and does **not** constitute an endorsement of these laboratories by FDA. Because methods may vary from laboratory to laboratory, the test data submitted to FDA should contain a brief description of the test protocol, scoring criteria used, and the method used for rating skin responses.

Primary Skin Irritation Test (Animal Study)

Skin irritation testing is performed to demonstrate the irritation potential of the gloves, i.e., for initiating or aggravating damage through its contact with the skin. Primary skin irritation testing is usually done according to the regulations of the Consumer Product Safety Commission, located at 16 CFR Part 1500. The purpose of the study is to determine the dermal irritation potential of the test article to intact and abraded skin of the rabbit.

The backs of six healthy albino rabbits are clipped free of hair. The skin is abraded in one area and left intact in the other. At least a 1 inch x 1 inch portion of the test article (piece of medical glove) is applied to each of two sites per rabbit. The inside and outside of the gloves should be identified such that both sides are tested, i.e., approximately half of the test articles expose opposite sides of the glove to the subject. The test article is covered by a double layer of surgical gauze. The gauze is covered with non-reactive adhesive tape and the entire test site is wrapped with an impervious cloth. The rabbits are returned to their cages.

The condition of the skin is then evaluated after 24 hours of exposure and again at 72 hours. The reactions should be scored according to the skin reaction values as stated under 16 CFR 1500.3(c)(4).

Dermal Sensitization Study (Animal Study)

Dermal sensitization is performed to demonstrate the potential of the device for eliciting a delayed hypersensitivity (Type IV) immunological response through its contact with the skin. This reaction is due primarily to substances which could leach out of a material. Guinea pigs are used because they have been shown to be the best animal model for human allergic contact dermatitis. Methodology for the study is illustrated under ASTM standard F-720-86, *Standard Practice for Testing Guinea Pigs For Contact Allergens, Guinea Pig Maximization Test*. Laboratories may also use the method of Buehler, as reported in *Archives of Dermatology* (1965). Dermal sensitization studies use 2 tests or phases: the induction phase and challenge phase. The inside and outside of the gloves should be identified such that both sides are tested, i.e., approximately half of the test articles expose opposite sides of the glove to the subject.

Induction Phase. In Buehler's method the hair is clipped from the mid-back area of 10 guinea pigs designated as test animals. At least a 1 inch x 1 inch sample of the test article, backed by at least a 1 inch x 1 inch gauze pad, is applied to the test area. The gauze pad is covered with non-reactive adhesive tape and wrapped with an elastic bandage.

Test articles are removed after 6 hours and observations for erythema and edema are recorded. The test article application procedure is repeated 3 times each week for 3 weeks until 9 applications are made to the test area.

Challenge Phase. Two weeks after application of the final induction test article, the hair of each guinea pig, including 5 additional untreated animals used as negative controls, is removed with a clipper from the mid-back area. At least a 1 inch x 1 inch piece of test article is applied to the shaved area of the test and control guinea pigs and taped in place. The trunk of each animal is wrapped with an elastic bandage to maintain the test article on the site. The test articles are removed after 6 hours. Then three observations for erythema and edema are made:

1. immediately after the challenge article is removed,
2. again after 24 hours, and
3. again after 48 hours.

Hypoallergenicity

Title 21 CFR 801.437 prohibits the use of the word "hypoallergenicity" on user labeling for natural rubber latex gloves distributed after September 30, l998. This includes gloves that have received prior 510(k) marketing clearance.

FDA does not currently require a new 510(k) submission for labeling changes made to comply with 21 CFR 801.437, provided that no other changes requiring a new 510(k) submission are made to the same device. However, the firm must keep appropriate records documenting the labeling changes.

Testing for Skin Sensitization to Chemicals

Please refer to the document titled, *"Draft Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Latex Products,"* available on the World Wide Web at: http://www.fda.gov/cdrh/ode/944.html.

If a manufacturer has already conducted a Modified Draize (MDT) test on a minimum of 200 human subjects to support a reduced sensitization claim, the MDT data may be used instead of the primary skin irritation test (animal) and dermal sensitization study (animal) typically used to support the general biocompatibility of medical gloves.

COLOR AND FLAVOR ADDITIVES

Manufacturers have the responsibility to demonstrate that color and flavor additives remaining in and on gloves are safe.

Color additive regulations are located in 21 CFR Parts 70 to 82 and flavor additive regulations are located in 21 CFR Part 172 Subpart F. These regulations define acceptable flavor and color additives. **The addition of color, flavor, or any chemical to a medical glove is considered to be a significant change which requires a premarket notification submission [510(k)].** Also, a 510(k) submission for a new glove or for a modification to an existing glove may be submitted according to the guidance titled, *The New 510(k) Paradigm - Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, available on the World Wide Web at: http://www.fda.gov/cdrh/ode/parad510.pdf.

The Medical Device Amendments of 1976 amended Section 721 of the Food, Drug, and Cosmetic (FD&C) Act to make color additives used in medical devices subject to the same provisions that apply to color additives in food, drugs and cosmetics. The FD&C Act provides that devices containing color additives are to be considered adulterated unless there is a regulation in effect that lists the color for such use. A so-called listing regulation identifies a color and prescribes a specific use. However, the FD&C Act limits the applicability of these provisions to only those color additives that are associated with devices that come in direct contact with the body for a significant period of time. The color additives listed in Subpart D or Parts 73 and 74 of 21 CFR belong to this category.

The color additive regulations for medical devices (21 CFR Parts 73 and 74) should not be confused with the general 510(k) requirements which are independent of the color additive listing and certification mentioned above. It is the manufacturer's responsibility to show that **any** substance added to a device, not necessarily limited to color additives, does not adversely affect the safety of the device. Therefore, if a device contains a color or other chemical additive and the device is intended to be in contact with the skin or other parts of the body, various biocompatibility data should be submitted to demonstrate the safety of the additives unless the manufacturer can establish that the additives would not leach and contact the body.

Medical device labeling requirements do not require on the glove box or carton an "ingredient statement" listing the flavor agent, colorant or other additives used in the manufacture of the glove.

NON-PYROGENIC

FDA does not believe that there is any medical basis for a non-pyrogenic claim for medical gloves, including surgeon's gloves.

The following list was compiled as an aid to the medical device industry. An attempt was made to compile an inclusive list from available public information sources. Inclusion of the name of a manufacturer on this list does not connote FDA recognition of their ability to adequately perform the services listed. As with any supplier of raw materials or services, it is the manufacturer's responsibility to determine and verify the adequacy of the services offered. See Chapter 10 and 21 CFR 820.30 and 820.50.

LABORATORIES THAT PERFORM ASTM DRAIZE TEST

Consumer Product Testing Co.
12 Spielman Road
Fairfield, N.J. 07004

Ph: 201-226-6146
FAX: 201-808-7234

Hilltop Pharmatest, Inc.
3333 Vine Street
Cincinnati, Ohio 45220

Ph: 513-281-2989
FAX: 513-281-0148

California Skin Research Institute (CSRI)
15222-B Avenue of Science
San Diego, CA 92128

Ph: 619-618-1328
Toll Free 800-808-2774
FAX: 619-618-1476
www.calskin.com

Contacts: Lawrence A. Rheins, Ph.D., President
Email: Irheins@calskin.com
Robert A. Harper, Ph.D., Exec. Vice President
Email: rharper@calskin.com
Vera B. Morhenn, M.D., Vice President, Scientific Affairs
Email: vmorhenn@calskin.com

Lab specialties: Predictive patch studies for medical devices; modified Draize-95 tests on human subjects

NOTE: To add your lab to this Draize test list, please supply formatted data as shown above, including your Email address, during the comment period.

The following list was compiled as an aid to the medical device industry. An attempt was made to compile an inclusive list from available public information sources. Inclusion of the name of a manufacturer on this list does not connote FDA recognition of their ability to adequately perform the services listed. As with any supplier of raw materials or services, it is the manufacturer's responsibility to determine and verify the adequacy of the services offered. See Chapter 10 and 21 CFR 820.30 and 820.50.

PRIMARY SKIN IRRITATION AND HUMAN DERMAL TOXICITY TEST LABS

AMA Laboratories, Inc.
216 Congers Road, Bldg. 1
New City, NY 10956
Ph: 914-634-4300
FAX: 914-638-4872

Contacts: Dr. Shyla Cantor, Study Director
David R. Winne, QA Supv.
Gabriel Letizia
Lab specialties: Human clinical testing only, modified Draize, 1 climate.

California Skin Research Institute (CSRI)
15222-B Avenue of Science
San Diego, CA 92128
Ph: 619-618-1328
Toll Free 800-808-2774
FAX: 619-618-1476
www.calskin.com

Contacts: Lawrence A. Rheins, Ph.D., President
Email: Irheins@calskin.com
Robert A. Harper, Ph.D., Exec. Vice President
Email: rharper@calskin.com
Vera B. Morhenn, M.D., Vice President, Scientific Affairs
Email: vmorhenn@calskin.com
Lab specialties: Predictive patch studies for medical devices; modified Draize-95 tests on human subjects

Clinical Research Laboratories, Inc.
371 Hoes Lane
Piscataway, NJ 08854 USA
Ph: 908-981-1616
FAX 908-981-0520

Contacts: Michael Muscatiello, Ph.D.
Lab specialties: Modified Draize, 1 climate

Concordia Research Laboratories, Inc.
248 Columbia Turnpike
Florham Park, NJ 07932 USA
Ph: 201-734-0734
FAX: 201-734-0334

Contacts: Dr. Guido Battista, President/Director Labs
Theresa Battista, Director, Applied Science
Lab specialties: Human patch testing, oral product research and evaluation, medical device evaluation (safety/efficacy/claim support); modified Draize, 1 climate.

Consumer Product Testing Company, Inc.
12 Spielnan Rd
Fairfield, NJ 07004 USA
Ph: 201-808-7111
FAX: 201-808-7234

Contacts: Allen L. Palanker, President
Melvin F. Weiss, Vice-President
Lab specialties: Pre-clinical safety and efficacy testing, human patch testing.

Contox, Ltd.
P.O. Box 368
Ft. Washington, PA 19034-0368
Ph: 610-277-2458 and
215-288-4882
FAX: 610-277-3980

Contacts: Karl L. Gabriel, Ph.D.
Fellow, American College of Clinical Pharmacology
David Gabriel, General Manager

Lab Specialties: Irritation (e.g., 21-day cumulative irritation), allergy (e.g., RIPT), phototoxicity and photoallergy, OTC Monographs, etc.; modified Draize. Human testing only.

Covance Laboratories
3301 Kinsman Boulevard
Madison, WI 53704 USA
Ph: 608-242-2622
FAX: 608-241-7227

Contacts: Mary L. Westrick, Executive Director
Clinical Research Unit – Madison
mary.westrick@convance.com
Matthew J. Palazzolo, Ph.D.
Vice President
matthew.palazzolo@Covance.com

Lab specialties: Clinical testing and research laboratory, safety and efficacy testing, sensory evaluation, patch testing, consumer use studies. No modified Draize studies.

Education & Research Foundation
2602 Langhorne Road
Lynchburg, VA 24501 USA
Ph: 804-847-5695
FAX: 804-846-1707

Contacts: Bert Mathews, Management Director and Vice President
Claire Whitmore, M.D., President
Lab specialties: Dermatology efficacy studies, patch, photopatch; modified Draize, 1 climate
Comments: Main site in Lynchburg; alternate site in Richmond, VA.

Essex Testing Clinic, Inc.
799 Bloomfield Avenue, Suite 212
Verona, NJ 07044 USA
Ph: 201-857-9541

FAX: 201-857-9662

Contacts: Dr. Michael Rozen
Dr. Harold Schwartz
Lab specialties: Human patch testing, all aspects of human safety/efficacy testing for cosmetics, drugs, etc.; modified Draize, 1 climate.

Harrison Research Laboratories, Inc.
2497 Vauxhall Rd
Union, NJ 07083 USA

email: HRLabs@aol.com
Ph: 908-688-7600
FAX: 908-688-7601

Contacts: Lynne B. Harrison, Ph.D., President
Alice V. Healy, R.N., Clinic Manager
Lab specialties: Human patch testing, efficacy/exaggerated-use tests, claim support; modified Drize, 1 climate.

Hill Top Research, Inc.
P.O. Box 429501
Cincinnati, OH 45242 USA

Ph: 513-831-3114
FAX: 513-831-1217

Contacts: J. James Pearce, Jr., President; John E. Wild, Vice-President
Lab specialties: Human dermal studies for OTC and RX drugs and personal care products, acute toxicology, sensory evaluation; modified Draize, 2 climates
Comments: Human studies are offered in Cincinnati, Ohio; St. Petersburg, Florida; West Palm Beach, Florida, Scottsdale, Arizona; East Brunswick, NJ; and Winnipeg, Manitoba, Canada.

Industrial Toxicology Research Centre
Mahatma Gandhi Marg
P.B.No. 80
Lucknow - 226 001 INDIA

FAX: 522-248227

Ivy Laboratories, Inc.
University City Science Center
3401 Market Street, Suite 226
Philadelphia, PA 19104 USA

Ph: 215-387-8400
FAX: 215-387-1046

Contacts: Claudette Leyden, CPA, President
Kays H. Kaidbey, MD, Medical Director
Lab specialties: Human safety and efficacy patch studies (maximization, irritation, phototoxicity, photoallergenicity). Human testing only.

MacWill Research Laboratories
564 Lee Street, S.W.
Atlanta, GA 30310 USA

Ph: 404-753-1226
FAX: 404-753-9599

Contact: Mr. Solomon McBride
Lab specialties: Skin irritation and sensitization; modified Draize,1 climate

NeuroCommunications Research Laboratories, Inc.
Vespucci Drive — Ph: 800-336-1935
Danbury, CT 06180 USA — Ph: 203-744-7474
FAX: 203-744-7488

Contacts: Curt Weinstein, President
Margaret Weinstein, B.S.R.N., Vice-President

North American Science Associates, Inc.
2261 Tracy Road
Northwood, OH 43619-1397 USA — Ph: 419-666-9455
FAX: 419-666-2954

Contact: Bill Roth
Email: broth@NAmSA.com
Lab specialties: Primary skin irritation; non clinical work only
Other locations: Kennesaw, Georgia; Irvine California

Organon Research Centre
7, Wood Street
Calcutta - 700 016 INDIA — FAX: 33-2473750

Paddington Testing Company, Inc.
1819 J.F. Kennedy Boulevard
Philadelphia, PA 19103 USA — Ph: 215-563-7330
FAX: 215-563-3044

Contacts: Carmela Ciferni, Resident Manager
Lab specialties: Human patch testing, cumulative irritancy, clinical trials and acceptance studies; modified Draize; 2 climates. Two labs in the U.S. plus cooperating laboratories in Europe, Asia, Africa, and South America.
Pharmaceutical and Cosmetic Evaluations (PACE) Division
Lab specialties: Sensory evaluations, damaged or irritated skin evaluations; modified Draize, 2 climates.

Product Safety Labs
A Division of Nutrition International
724 Cranbury Road — Ph: 800-425-0002
East Brunswick, NJ 08816-3206 USA — Ph: 732-254-9200
FAX: 732-254-6736

Contacts: Walter Newman, MS, Director, Sales/Marketing
Lab specialties: Rabbit skin irritation and sensitization; modified Draize; 2 climates.

Herbert V. Shuster, Inc.
5 Hayward Street
Quincy, MA 02171 USA — Ph: 617-328-7600
FAX: 617-770-0957

Contacts: Nancy Davis

Lab specialties: Performance/efficacy testing, human studies, patch testing; modified Draize.
Comments: Additional facility located in Atlanta, Georgia.

STS, Inc.
P.O. Box 349
7500 West Henrietta Rd. Ph: 716-533-1672
Rush, NY 14543 FAX: 716-533-1796

West Coast Analytical
9840 Alburtis
Santa Fe Springs, CA 90670 Ph: 562-948-2225
FAX: 562-948-5850

Contact: Eric Lindsay
Email: eric.lindsay@WCASlab.com
Lab specialty: Analytical testing only

PPD Pharmaco International
Ph: 44(0) 1245-252878
Townfield House, 30-33 Townfield Street FAX: 44(0) 1245-490451
Chelmsford, Essex, CM1 1QL England

Contacts: David B. Davies, BSc, MBA
david.davies@europe.ppdi.com
Lab specialties: Patch testing (acute, RIPT, maximization, etc.).
Comments: Other locations: Cambridge, UK; Chelmsford, UK; Leicester, UK; Southampton, UK; Stockholm, Sweden; Brussels, Belgium; Warsaw, Poland; Karlsruhe, Germany; Gentilly, France; Madrid, Spain; Sidney, Australia; Prague, Czech Republic; Johannesburg, South Africa.
U.S. Locations: Austin, Texas; Richmond, Virginia; Columbia, Maryland; Arlington, Virginia; Research Triangle Park, North Carolina; Princeton, New Jersey.

Haffkine Institute for Training, Research & Testing
Acharya Dandi Marg, Parel,
Bombay - 400 012 INDIA

Inveresk Research International Ltd.
Corporate Headquarters Ph: 44(0)1875 614545
Tranent EH33 2 NE FAX: 44(0)1875 614555
Scotland
Contacts: Dr. Ian P. Sword, Managing Director
Dr. A. B. Wilson, Group Head Toxicology
Lab specialties: Product safety -- skin irritation/delayed contact allergy potential offices in Tokyo, Japan; Frankfurt, Germany; Paris, France; and Falls Church, Virginia, USA.

Huntingdon Life Sciences, Ltd.
Woolley Road
Alconbury Ph 44(0) 1480 892 000
Huntingdon FAX: 44(0) 1480 892 205
Cambs. PE17 5HS England

Lab specialties: Long & short term toxicology, metabolic studies, environmental studies, pharmacology, reproductive & mutagenicity studies; no modified Draize studies
Labs located in Huntington, Cambridgeshire; Eye, Suffolk; Wilmslow, Cheshire; and Princeton, New Jersey, USA

SGS U.S. Testing Company, Inc.
291 Fairfield Avenue
Fairfield, NJ 07004 Ph: 973-575-5252
FAX: 973-244-1823

Contact: Dan Drozdowski Email: Dan_Drozdowski@sgsgroup.com
Dominick Lepore Web: www.ustesting.sgsna.com
Lab specialties: Biocompatibility tests--primary eye and skin irritation, skin sensitization, intracutaneous and systemic toxicity texts, hemolysis; select panel, human patch tests, irritation and sensitivity; cytotoxicity. Protein assay (modified Lowry assay for soluble protein in latex); physical/chemical tests; performance tests, compatibility testing vs. lotions, germicides used in health settings.

Shriram Institute for Industrial Research
19, University Road Ph: 91-11-725-7267, 725-7860
Delhi-110007 INDIA FAX: 91-11-725-7676

Contact: Mr. K.M. Chacko, Assistant Director & Chief Toxicology
Lab specialties: modified Draize, 2 climates

NOTE: To add your lab to this toxicity test list, please supply formatted data as shown above, including your Email address, during the comment period.

Reference to ASTM Test Lab Directory

This directory is listed as an aid to the medical device industry. Inclusion of the name of a company does **not** connote FDA recognition of their ability to adequately perform the services listed. As with any supplier of services, it is the manufacturer's responsibility to determine and verify the adequacy of the services offered. See 21 CFR 820.30 and 820.50.

The Association for Testing and Materials (ASTM) has a directory, the International Directory of Testing Laboratories, which lists the locations and capabilities of testing laboratories that perform services for a fee. The information on the types of tests performed, materials analyzed, or other services offered is based on questionnaires signed and submitted by officers of the laboratories. Each laboratory pays a fee for the annual listing.

Starting with the 1988 edition, this Directory became an annual ASTM publication. The 1997 edition includes these features:

- geographical segmentation of listings by country, state and city
- phone/FAX/E-Mail numbers and contact name for each laboratory
- 16 fields of testing
- 7 classifications of laboratory services
- 12 major categories with 58 subcategories of materials and products
- number and type of professionals at each site
- branch locations of laboratories
- two narrative sections that describe the laboratories specialty, equipment, testing capabilities and applications
- three indexes-subject, tests performed, alphabetical
- specific tests performed (listed by issuing agency and designation number)

The Directory contains two sections-laboratory listings and indexes. The laboratory listings appear geographically so that you can easily scan and select the one or more laboratories in your geographic area that handle the product or service required. Each laboratory has an assigned laboratory number. The indexes in the Directory use this assigned laboratory number when referring to the specified laboratory.

Further information on the services of listed laboratories should be obtained directly from the listees. Direct any questions on using the Directory or including your laboratory's services in the 1998 edition to: Judy Helm, Marketing Department, ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959 (phone 610-832-9610). Inquiries about purchasing this Directory or other ASTM publications should be directed to ASTM Customer Service at 610-832-9585.

ASTM has not attempted to investigate, rate, endorse, or place a seal of approval upon any laboratory. Nor does ASTM vouch for the qualification of the individual laboratories. Therefore, this Directory is not intended, and should not be used, as an ASTM certified laboratory list of laboratories offering their services for either government or private work.